National Institute on Aging (NIA) IMbedded Pragmatic Alzheimer’s Disease (AD) and AD-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory (NIA U54AG063546)

OVERVIEW OF 2020 PILOT AWARD RFA 2A

Ab Brody, PhD, RN, FAAN
NIA IMPACT Collaboratory Pilot Core Lead
Associate Director, Hartford Institute for Geriatric Nursing
Associate Professor of Nursing and Medicine,
New York University Rory Meyers College of Nursing
Mission
To build the nation’s capacity to conduct ePCTs of interventions within health care systems (HCS) for people living with dementia (PLWD) and their care partners

Values
Be Collaborative
Be Generative
Be Inclusive
Be Excellent
Be Transformative
Be Sustainable

Vision
To transform the delivery, quality, and outcomes of care provided to PLWD and their care partners by accelerating the testing and adoption of evidence-based interventions in HCS
Governance Structure
Leadership

Susan Mitchell, MD, MPH
Principal Investigator
Professor of Medicine, Harvard Medical School
Senior Scientist, Hebrew SeniorLife
Marcus Institute

Vincent Mor, PhD
Principal Investigator
Florence Pirce Grant University Professor
Professor of Health Services, Policy and Practice
Brown University School of Public Health

Ellen P. McCarthy, PhD, MPH
Executive Director
Associate Professor of Medicine, Epidemiology
Harvard Medical School
Associate Scientist, Hebrew SeniorLife
Marcus Institute

Jill Harrison, PhD
Executive Director
Associate Professor of Health Services, Policy and Practice
Brown University School of Public Health
# Pilot Core

<table>
<thead>
<tr>
<th>Executive Committee</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ab Brody, PhD, RN, FAAN – Lead</strong></td>
<td>Associate Professor and Associate Director, Hartford Institute for Geriatric Nursing, NYU Rory Meyers College of Nursing <em>(Geriatric and Palliative Nursing)</em></td>
</tr>
<tr>
<td><strong>Kathleen Unroe, MD, MHA – Associate Lead</strong></td>
<td>Associate Professor, Indiana University Department of Medicine, Indiana University Center for Aging Research, Regenstrief Institute <em>(Geriatrician)</em></td>
</tr>
<tr>
<td><strong>Deborah Barnes, PhD, MPH</strong></td>
<td>Professor, Psychiatry, Epidemiology &amp; Biostatistics, UCSF San Francisco VA Health Care System <em>(Epidemiologist, Health Services)</em></td>
</tr>
<tr>
<td><strong>Joshua Chodosh, MD, MSHS</strong></td>
<td>Professor of Medicine and Population Health, NYU School of Medicine <em>(Geriatrician, Health Services)</em></td>
</tr>
<tr>
<td><strong>James Galvin, MD, MPH</strong></td>
<td>Professor of Neurology, University of Miami Miller School of Medicine <em>(Neurology)</em></td>
</tr>
<tr>
<td><strong>Kenneth Hepburn, PhD</strong></td>
<td>Professor, Nell Hodgson Woodruff School of Nursing, Emory University <em>(Social Scientist)</em></td>
</tr>
<tr>
<td><strong>Andrea Troxel, ScD</strong></td>
<td>Professor of Population Health and Director of Biostatistics, NYU School of Medicine <em>(Biostatistics)</em></td>
</tr>
</tbody>
</table>
2020 Pilot Grants Program Request for Applications
Request For Applications - Cycle 2A

IMPACT Collaboratory will solicit and fund:

Pilot studies to generate preliminary data necessary to design and conduct a future full-scale ePCT of non-pharmacologic interventions in HCS for people living with AD/ADRD and their care partners.

In response to the coronavirus disease (COVID-2019) outbreak, in this award cycle, the IMPACT Collaboratory will prioritize applications proposing pilot ePCTs of telemedicine, telehealth, and remote technologies interventions aimed at improving the health care, unmet needs, quality of life and/or health outcomes for people living with AD/ADRD and their care partners.
Requirements

Pilot Studies must:

• Pilot test a non-pharmacological intervention targeting people living with AD/ADRD and/or their care partners using an embedded pragmatic trial design.

• Implement intervention in ≥2 HCS or sites (e.g., nursing homes, hospitals, healthcare provider practices). Randomization is NOT required.

• Evaluate an intervention with a reasonable evidence-base demonstrating its efficacy as described in the RAPT Model paper. Telemedicine, telehealth, and remote technologies interventions will be prioritized.

• Be no more than minimal risk to human subjects.

Readiness Assessment for Pragmatic Trials (RAPT)
Requirements continued

• Be feasible within the one-year time-frame.

• Designed to qualify for a waiver or alteration of informed consent.

• Have a single, primary clinical outcome that can be collected pragmatically.

• Have high alignment with stakeholder priorities. Stakeholders include but are not limited to: PLWD, care partners, frontline providers, healthcare systems, and/or payers.

• Include a qualified biostatistician on the research team.
Stage of Research and Outcomes

Stage of Research

• Pilot studies should enable the researchers to carry out a Stage IV effectiveness trial aligned with the NIA Stage Model

Primary and Secondary Outcomes

• Primary clinical outcome must be collected pragmatically
• Secondary outcomes evaluating the implementation experience and other clinical outcomes are encouraged.
• The pilot study is NOT expected to be powered to demonstrate an effect of the intervention.
Additional Key Methodologic Considerations of a Pilot for an ePCT

In Preparation for a full-scale ePCT, the following may be appropriate:

• Refining approach to implementation of prior developed intervention
• Identification and enrollment of participants
Health Equity

• Health equity considerations must be integrated in the Research Plan.

• Rationale should be provided about how aspects of the design (for example, selection of health care system location, target study population demographics, and/or tailoring of the intervention to different cultures) are and are not relevant to people from diverse backgrounds.

• While it may not be possible to address all issues within the limited scope of a pilot study, at minimum, a description should be provided about how the pilot study experience will inform the design of future larger ePCT in terms of its relevance to people from diverse backgrounds who are living with dementia and/or their care partners.
Budget

- One-year project period, non-renewable.
  - No-cost extensions are generally not allowed, but will be considered only in exceptional circumstances, require NIA approval, and are not guaranteed.

- Up to $175,000 (direct costs)

- Follows NIH rules and regulations regarding allowable costs

- Up to 2 Subawards allowed
  - Whenever feasible, purchase of services/consulting agreements are strongly preferred to subawards.
Eligibility

• U.S. Institutions Only – *all work must be performed within the U.S.*

• Eligible Applicants:
  
  • Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their organization to develop an application.

  • Hold a faculty or research scientist position at an eligible institution by the start date of the award or be otherwise eligible to serve as a Principal Investigator as determined by their organization.

  • Must be citizens or permanent residents of the United States.

  • Applicants from under-represented racial and ethnic groups and individuals with disabilities are strongly encouraged to apply for funding.
Application Process

Two Step Application Process

STEP 1: Letter of Intent (LOI) – due May 29, 2020 at 5pm ET

STEP 2: Full Proposal Application – by Invitation Only

• Only one Principal Investigator allowed (no Multiple PIs/PDs)

• Only one LOI allowed per Principal Investigator per cycle
Step 1: Letter of Intent

Main Elements

- Pilot Study Description (2 pages):
  - Background/rationale
  - Specific aims
  - Design overview
  - Setting (types and names of healthcare systems)
  - Participants and participant identification strategy
  - Intervention structure and implementation strategy
  - Outcome definitions and collection methods

DUE MAY 29, 2020 AT 5PM ET

Review by an interdisciplinary review committee based on:

- Responsiveness to RFA and mission of IMPACT Collaboratory
- Scientific impact and potential to lead to full-scale ePCT
- Feasible in the one-year timeframe
LOI Application main elements continued

- Completion of the LOI Pilot Study Pragmatic Design Worksheet
- Attestation in UFunds that Principal Investigator has read and/or viewed the following materials*:
  - Viewed the video “Pragmatic Clinical Trials: How Do I Start?”
  - Read the RAPT Model paper OR viewed the IMPACT Collaboratory Grand Rounds on “Are you ready for a pragmatic trial? The RAPT Model and implementation considerations.”
  - Read the PRECIS-2 paper
- PI’s NIH Biosketch
- Whether Subawards are anticipated

*Materials are located at: https://impactcollaboratory.org/pilot-required-materials-and-resources/
Online Submission & Access to UFunds

- LOIs must be submitted **online via UFunds** grant applications system:
  https://ufunds.brown.edu/

- Applicants **without** a Brown University email address **must FIRST request access** to the UFunds system using a Gmail (Google) account at:
  https://tinyurl.com/UFundsAccess

  *Request process takes up to 2 business days → If you are THINKING OF APPLYING → PLEASE REQUEST ACCESS NOW*

- Applicants will be notified at their Gmail address once access has been granted

- LOIs will not be accepted after deadline because an applicant did not request access in a timely fashion
LOI to Full Proposal Stage

LOIs Notifications:

• LOI notifications by June 19, 2020

• Applicants invited to submit a full proposal will:
  - Be granted access to Brown UFunds full application system
  - Meet with a consultative team for guidance and advice in developing the full proposal e.g., advice on design, measurement, dissemination and implementation, health equity, stakeholder engagement, and use of Collaboratory resources such as data sources and healthcare systems that may be willing to participate in a pilot study

• Full proposal applications are due **September 4, 2020 @ 5pm ET**
Step 2: Full Proposal (by invitation only)

Requirements

• Abstract (max 300 words)
• Specific Aims (1 page)
• Research Plan - follow NIH R21 format (6 pages)
  o Background and Significance
  o Preliminary Studies (if applicable)
  o Research Design and Methods, including:
    - Study population
    - Setting (sites/health care systems)
    - Randomization scheme and masking when appropriate (not expected for all pilot studies)
    - Intervention structure, implementation protocol, and fidelity/adherence monitoring plan
    - Data sources, elements, and collection protocol
    - Analytic plan

* Health equity considerations must be integrated in the research design and methods.
Full Proposal Research Plan continued

IMPACT Collaboratory-specific additions:

- **Milestones**: Specify quarterly milestones that are specific and measurable by which your progress can be reviewed.

- **Future Directions and Next Steps**: Specify how the pilot study will directly inform the development of a full-scale, Stage IV effectiveness ePCT (on the NIH Stage Model) application to the NIH or other funding sources and the anticipated timeline to apply for such funding.
Full Proposal Requirements continued

Additional Full Proposal Requirements:

Letters of Support from each participating healthcare system/site stipulating that the proposal has high alignment with:

1) Priorities of the health care system in caring for PLWD and/or their care partners or addressing the care of PLWD and their care partners in the milieu of COVID-2019 outbreak

and

2) Strong likelihood the intervention could be feasibly integrated and adopted into the clinical flow by frontline providers.
Full Proposal Requirements continued

• PHS Human Subjects and Clinical Trial Information
• Pilot Study Pragmatic Design Worksheet
• NIH Biosketch for the PI and Key Personnel
  Note: The research team must include a qualified biostatistician as co-investigator or consultant.
• Acknowledgment Letter from IRB/HRPP Official.
• Bibliography and References Cited. Appendices are NOT permitted.
• Budget detailing research-related expenses and salary support with an accompanying budget justification
Scientific Merit Review Criteria and Process

Scientific merit will consider:

1) Fit with the IMPACT Collaboratory’s mission
2) Significance
3) Intervention readiness for a pilot ePCT based on the RAPT Model
4) The pragmatic nature of pilot study design based on the PRECIS-2 framework
5) Integration of health equity in the research plan
6) Investigator qualifications
7) Environment
8) The likelihood that the pilot study will lead to successful future extramural grant funding for a full ePCT
9) Appropriateness of the budget and human subjects protections.
Proposals Recommended for Funding

If an application is recommended for funding, the PI will have to submit the following within 2 weeks:

• Updated Human Subjects and Clinical Trial Information (e.g., Forms Version F)

• IRB Application (with guidance from IRB Team)
  - PIs do not need to budget funds for the IRB.

• Data Safety Monitoring Plan (DSMP) and Charter (templates provided)

• Clinical Intervention Study Protocol (template provided)

*The IMPACT Collaboratory Administration Core will assist the PI with the materials requested.*
Requirements of Funded Applications

1. Pilot studies must adhere to IRB, Data and Safety Monitoring, and Data and Resource Sharing policies.

2. Complete Financial Conflict of Interest assurance and training in accordance with NIH policies.

3. Register with ClinicalTrials.gov in accordance with NIA guidelines.

4. Monthly meeting with assigned EC member of the Pilot Study Core

5. Engagement in IMPACT Collaboratory, including:
   - Participation in Core Groups and Teams
   - Attend regular webinar-based Grand Rounds
   - Attend and present at in-person IMPACT Collaboratory Scientific Meeting
Requirements of Funded Applications continued

6. Submit required reports for study tracking and standardized data elements on quarterly basis, as well as a final report at the end of the pilot study year.

7. Follow IMPACT Collaboratory invoicing guidelines.

8. Provide budget reports upon request and at the end of the pilot study year.

9. Adhere to the IMPACT Collaboratory publication policy and acknowledge sponsorship in all presentations, publications, and subsequent grants stemming from this pilot study.

10. Respond to IMPACT Collaboratory queries for information after project ends.
## Key Dates

<table>
<thead>
<tr>
<th>Key Dates – IMPACT Collaboratory Pilot Awards 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RFA Release Date</strong></td>
</tr>
<tr>
<td><strong>Letter of Intent Application – Opens</strong></td>
</tr>
</tbody>
</table>
| **Informational webinars**                      | April 28, 2020 at 1:30pm ET  
May 6, 2020 at 4:00pm ET |
| **Letters of Intent Due Date – Required**       | May 29, 2020 at 5:00pm ET |
| **Letters of Intent – Notification**            | June 19, 2020 at 5:00pm ET |
| **Full Proposal Application Due Date**          | September 4, 2020 at 5:00pm ET |
| **Earliest Study Start Date**                   | January 2021 |
For answers to Frequently Asked Questions, visit our website:

https://impactcollaboratory.org/pilot-grant-faq/
QUESTIONS?

Send us an email:
IMPACTcollaboratory@hsl.harvard.edu
Thank you!

2020 Pilot Grant Program
Request for Applications
LOI Due May 29, 2020 at 5:00pm ET

Contact Us: IMPACTcollaboratory@hsl.harvard.edu